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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/743,787	01/06/2004	Alberto Guillermo Suzarte Paz	024273-00001	8586

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EXAMINER	
ROGERS, JAMES WILLIAM	

ART UNIT	PAPER NUMBER
1618	

NOTIFICATION DATE	DELIVERY MODE
01/28/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DCIPDocket@arentfox.com
IPMatters@arentfox.com
Patent_Mail@arentfox.com

Office Action Summary	Application No.	Applicant(s)	
	09/743,787	SUZARTE PAZ ET AL.	
	Examiner	Art Unit	
	James W. Rogers, Ph.D.	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 November 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7-12* is/are pending in the application.

4a) Of the above claim(s) *7-10* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11 and 12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *17 January 2001* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *01/06/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of group I in the reply filed on 11/21/2007 is acknowledged. The traversal is on the ground(s) that a search for new claims are directed to a product, a process of manufacture and use relating to polyvinyl acetates should not be restricted as supported within MPEP 1850(III)(A). This argument is not found persuasive. Firstly groups II,IV and VI are now moot due to applicants amendment. Group I from the previous office action pertained to the use of a polyvinylacetate (PVAc), claims 11-12 are drawn to a method of producing pharmaceutical preparations, the pharmaceutical preparations are a use of the PVAc, therefore from the previous election restriction only claims 11-12 are within the scope of previous group I. Claims 7-9 a process for obtaining PVAc and claim 10 PVAc produced by the process of claim 7 are most closely associated with previous group III, a process for obtaining PVAc. As pointed out in the previous office action the inventions listed as Groups I,III and IV do not relate to a single general inventive concept under PCT Rule 13.1 because JP55092655 (cited by applicants) teaches the use of PVAc in chewing gum but does not teach the same process to make PVAc as within claim 7. Therefore while JP55092655 pertains to the use of PVAc polymers as in group 1, it does not recite the additional elements of groups II-VI thus the groups above lack the same or corresponding special technical features. The examiner has withdrawn claims 7-10 for pertaining to an unelected invention.

The requirement is still deemed proper and is therefore made FINAL.

Drawings

New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because FIG 6 is not in English. Applicant is advised to employ the services of a competent patent draftsperson outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Specification

The abstract of the disclosure is objected to because the specification is generally narrative and indefinite, failing to conform with current U.S. practice. It appears to be a literal translation into English from a foreign document and is replete with grammatical, spelling and idiomatic errors. Due to time constraints the examiner cannot site all of the grammatical and spelling mistakes but invites applicants to review the application and correct it on their own time, without adding new matter to the specification. Correction is required. See MPEP § 608.01(b).

Claim Objections

Claim 11 is objected to because of the following informalities: Granulates is listed twice in line 3 of the claim. Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yang (US 4,740,376).

Yang discloses encapsulation of active ingredients (including pharmaceutically active ingredients such as drugs) within PVAc and a plasticizer. See abstract, col 1 lin 10-24, col 5 lin 7-38 and col 8 lin 36-55. Regarding applicants limitation that the PVAc is the same as claimed within claim 10, the MW of the PVAc within Yang was preferably

about 40,000 Da, within applicants claimed range. See col 4 lin 15-24 and col 6 lin 50-57. Since the MW of PVAc of Yang is within the range of applicants claimed invention it is obvious that the PVAc of Yang will have the same glass transition temperature of applicants claimed invention because the same polymer will obviously have the same properties including Tg. Since the compositions of Yang were produced in a melt it is assumed that any water would have been evaporated, thus the water content of PVAc would obviously be less than 1.5%. See col 5 lin 32-38. Regarding the other limitations on PVAc which limit the amount of residual monomer, acidic acid and peroxide content, it is assumed by the examiner that since the compositions of Yang were used in orally deliverable forms the amount of impurities and contaminates within the PVAc would be very low. It is considered to be ordinary and routine experimentation by one of ordinary skill in the art to purify a polymer to a high degree if it is to be used in an orally administrable dosage form.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sa (Drug Development and Industrial Pharmacy, 17(6), 893-900 (1991), cited by applicants).

Sa discloses Polyvinylacetate (MW=40,000 Da) microspheres containing theophylline. See entire disclosures especially page 894 lines 1-23 and table 1. Since the MW of PVAc of Sa is within the range of applicants claimed invention it is obvious that the PVAc of Sa will have the same glass transition temperature of applicants claimed invention because the same polymer will obviously have the same properties including Tg. Since the microspheres of Sa were dried in vacuum desiccator it is

assumed by the examiner that the amount of residual water would be less than 1.5%. Regarding the other limitations on PVAc which limit the amount of residual monomer, acidic acid and peroxide content, it is assumed by the examiner that since the compositions of Yang were used in orally deliverable forms the amount of impurities and contaminates within the PVAc would be very low. Also Sa discloses that acidic acid was used to dissolve PVAc and was evaporated off, therefore the examiner assumes the concentration of acetic acid would be essentially zero. It is considered to be ordinary and routine experimentation by one of ordinary skill in the art to purify a polymer to a high degree since the polymer is used to control the release of an active in a pharmaceutical compound.

Claim 11-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yang (US 4,740,376) in view of Sa (Drug Development and Industrial Pharmacy, 17(6), 893-900 (1991)).

Yang is disclosed above. Yang discloses that the amount of PVAc to plasticizer is between 5:1 to 1:5, preferably 1:2 to 2:1, thus the amount of PVAc present in the encapsulation portion can be 66% for instance (2:1 PVAc to plasticizer) higher than 60% weight of the controlled release matrix as recited within claim 12. See col 4 lin 29-32.

Yang while disclosing PVAc in the proportion to other ingredients in the controlled release matrix as claimed by applicants, does not disclose using PVAc in an amount of the overall composition between 2-25 wt%.

Sa is disclosed above. Sa discloses the use of drug in amounts up to 69.15% of the total composition. By combination since Yang discloses the use of PVAc in numerous ranges, for instance 66% and Sa discloses the use of active within PVAc composition in amounts up to 69.15% the combination would yield a particle containing higher than 60% of the controlled release portion and PVAc within applicants claimed concentration for the entire dosage form. Thus from the disclosures of Yang and Sa one skilled in the art at the time of applicants claimed invention could have envisioned the proportions of active ingredient, PVAc and other binders within applicants claimed range. One with skill in the art would have had a reasonable expectation of success in combining the dosage forms above because both are drawn to controlled release pharmaceuticals containing PVAc and the combination would have yielded predictable results to one of skill in the art. Thus the claimed invention would have been *prima facie* obvious since all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

Conclusion

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers, Ph.D. whose telephone number is (571) 272-7838. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MICHAEL P. HARTLEY
SUPERVISORY PATENT EXAMINER